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ORIGINAL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

LASANDRA MADDEN, Individually, and on Behalf of LABREA WILLIAMS, a minor child	§	
Plaintiff,	§	CIVIL ACTION No. 3:03-CV-0167-BD
v.	§	
WYETH, d/b/a WYETH, INC., f/k/a AMERICAN HOME PRODUCTS CORPORATION; WYETH CONSUMER HEALTHCARE, AN UNINCORPORATED DIVISION OF WYETH, f/k/a WHITEHALL-ROBINS HEALTHCARE; & WHITEHALL LABORATORIES, INC.	§	
Defendants.	§	

BRIEF IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' OMNIBUS MOTION FOR SANCTIONS AND TO COMPEL

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BRIEF IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' OMNIBUS MOTION FOR SANCTIONS AND TO COMPEL

TO THE HONORABLE UNITED STATES MAGISTRATE JUDGE KAPLAN:

Defendants (collectively "Wyeth") file this Brief in support of their response to Plaintiffs' Omnibus Motion for Sanctions and to Compel (the "Motion"):

I. INTRODUCTION

Plaintiff's immediate request for "death penalty" sanctions promises a chronicle of egregious discovery abuses. The Motion and its supporting appendix, however, are empty of substance. Indeed, the boldest charge Plaintiff levels—that Wyeth's representative lied to the Court under oath—is, in fact, founded on the qualified statement "Your Honor, not that I'm aware of," a statement that is actually true. Plaintiff's Motion recites false accusations and minor discovery complaints, some of which could have been resolved had Wyeth been given the opportunity. None of Plaintiff's scattershot accusations justifies the imposition of sanctions.

Plaintiff possesses many of the documents she alleges Wyeth is hiding. Moreover, several documents have now or will soon be produced to her, as promised by Defense counsel before the filing of the Motion. Plaintiff's Motion demonstrates a lack of understanding of the documents she has and yet a desire to obtain even more. Plaintiff's goal appears to be to gain leverage over Wyeth through greater discovery burdens, and their attendant costs, rather than proceeding to a trial of her claims on their merits.

Plaintiff served numerous extensive discovery requests on Wyeth. Wyeth responded to those requests in accordance with the Federal Rules of Civil Procedure and this Court's orders, producing almost 160,000 documents. Plaintiff's discovery responses, minimal compared to Wyeth's, have their own deficiencies; yet, Wyeth has chosen not to engage in meaningless discovery battles. There comes a time in every case for the documentary discovery process to cease and the case to be tried on the merits. This point has long passed in this case.

II. BACKGROUND

Plaintiff filed this case on February 2, 2003, and in March 2003 served a set of interrogatories with extensive subparts and the first of seven sets of requests for production. All tolled, Plaintiff served 95 interrogatories, 133 requests for admission ("RFA"), and 149 requests for production ("RFP"). *See* Appendix to Plaintiff's Motion ("PA") at 30-55, 648-716, 730B-81. Wyeth prepared and served written responses to the interrogatories and requests and, as of the filing of this Brief, produced more than 159,600 pages of documents from numerous facilities in the United States and many foreign affiliates. Wyeth also provided an electronic data extract from its proprietary Safety Surveillance System ("S^3") database at its own cost.

A. Wyeth's Safety Review Documents

Plaintiff's 1st RFP Nos. 34 and 35 sought Children's Advil safety studies and product safety committee reports, respectively. PA at 54. In response, Wyeth directed Plaintiff to the

New Drug Application ("NDA") for Children's Advil where the relevant studies could be found. PA at 54. As a result of a conference between the parties, Wyeth agreed to produce any studies responsive to RFP No. 34. PA at 104.

Subsequently, in response to more specific requests, 3rd RFP Nos. 9 and 10, Wyeth located documents relating to its Post-Marketed Safety Review meetings that in hindsight are also responsive to 1st RFP No. 35. Those documents were created in connection with the periodic meetings of Wyeth's attorneys and others that are held to discuss drug safety issues and whether others should address the products' global labeling documents. *See* Defendants' Appendix, incorporated herein by reference, ("DA") at 1-23; 25-26 ¶ 6. Because safety review documents include confidential communications between Wyeth's representatives and its attorneys for safety, regulatory compliance and the rendition of legal services, Wyeth withheld those documents as privileged and listed them on the privilege log Plaintiff requested. *See* PA at 435-90. An amended privilege log was served in November 2005. DA at 28-68.

B. Wyeth's Adverse Event Database

Interrogatory Nos. 5 and 6 and 1st RFP No. 20 sought information about and documents from Wyeth's adverse event database. PA at 35, 51. S^3 is the only database that monitors and maintains ADE reports. DA at 69 ¶ 2. All Children's Advil ADE reports, regardless of the databases in which they were processed in the past, are in S^3. PA at 273; DA at 69-70 ¶ 3-6.

ADE information comes to S^3 from myriad sources. Pursuant to Wyeth Policy 405, *all* Wyeth employees worldwide who become aware of adverse event information associated with a Wyeth product must transmit that information to its Global Safety Surveillance, Epidemiology and Labeling ("GSSEL"), department, formerly Global Safety Surveillance and Epidemiology ("GSSE"). PA at 61-82; *see also* DA at 72 ¶ 2.

Wyeth's call centers for product questions and complaints also receive ADE information. Wyeth maintains information relating to telephonic questions concerning its *prescription* products in a database known as MAGIC, the successor to a database called MADIRA. DA at 69 ¶ 2. MAGIC and MADIRA contain no Children's Advil ADE information. DA at 70 ¶ 6.

Wyeth's WATSIN database tracks complaints and questions regarding over-the-counter ("OTC") products and complaints about prescription products. DA at 69 ¶ 2. Complaints include calls such as consumers' requests for refunds. *See* PA at 236. ADE information that came into MADIRA was input into CDSSS and ADE information that comes into MAGIC or WATSIN, is transmitted to GSSE for inclusion in the S^3 database. DA at 70 ¶ 4-6.

Once ADE information arrives in GSSEL, it goes through various stages of review, but the ADE report is not considered "complete" until the medical reviewer or a specialist deems it to be so. DA at 75-76 ¶ 4. This complete ADE is the first ADE version. *Id.* If new information or additional source documents are received later, a new version is created. *Id.* All versions are saved in S^3. *Id.; see also* PA at 227. Data from earlier versions are copied to subsequent versions and any removed or "voided" information is preserved in S^3. DA at 76 ¶ 5.

Accordingly, in response to the Interrogatory Nos. 5 and 6, Wyeth identified and described S^3. PA at 35. Wyeth also identified WATSIN but not MADIRA, which relates to prescriptions and includes no mention of Children's Advil. PA at 35; DA at 70 ¶ 6. Wyeth objected to producing "all drug defect, customer complaint, or adverse drug experience data bases" as unduly burdensome and irrelevant, but did produce hard copies of draft MedWatch forms for Children's Advil relating to adverse skin reactions. PA at 51; DA at 76 ¶ 6-7.

C. Discovery Disputes and Hearings

Because Plaintiff challenged Wyeth's responses to the first discovery requests, the parties conferred twice and reached agreements on several issues relevant to the Motion. PA at 100.

The issues on which agreement could not be reached were briefed in a joint status report ("JSR") and submitted to the Court. PA at 99-143. Following a hearing on November 21, 2003, this Court issued an order on December 8, 2003 allowing either: a) Plaintiff's chosen expert supervised access to the "S^3, and WATSIN databases;" or b) a deposition of Wyeth's information systems manager. PA at 194. Wyeth then filed a motion for clarification because any access to its databases would be burdensome, disclose Wyeth's proprietary, trade secret information, and violate federal regulations regarding patient and reporter identifying information.

At the January 9, 2004 hearing on Wyeth's motion, Gerard Boccuti, Wyeth's litigation support manager and counsel, testified about the ADE database, stating — "The ADE database which we refer to as S Cubed . . . maintains all the adverse events of the product in the company . . ." PA at 214. Asked about WATSIN and whether it includes ADE reports, Boccuti explained that ADE information input into WATSIN is transferred to S^3. PA at 223. In response to the Court's question as to whether there were "databases out there that we haven't heard about yet that remotely touches on an adverse event report?" Boccuti responded "Your Honor, not that I am aware of." PA at 244.

To protect the proprietary and confidential nature of the information in S^3, Wyeth offered to make an extract of the responsive Children's Advil ADEs, redact the confidential information, and provide the extract to Plaintiff. PA at 211-12, 217-18. Because S^3 contains all ADEs for Children's Advil, preparing such an extract from S^3 would provide Plaintiff with all of the responsive ADEs. *See id.* The Court agreed and ruled that confidential patient and report information could be redacted from the S^3 extract. PA at 253-54, 268.[1]

[1] Safety review documents and foreign labeling were not addressed at the hearing. *See* PA 207-67.

On January 15, 2004, this Court ordered Wyeth to: (1) produce S^3 in an electronic form for the scope of discovery set by the previous order; (2) produce electronic data from the CAMP 1 and 2 studies within the scope of discovery previously set; (3) produce hard copies from the Documentum database of underlying records for the ADE reports within the same scope; and (4) provide an audit trail of any patient or reporter identification information redacted sufficient to show what was redacted, by whom and why. PA at 268-70.

D. Further Document Production

Pursuant to the Court's order, Wyeth redacted patient and reporter information from the relevant ADE reports and ADE source documents, and produced those documents in the first quarter of 2004. DA at 78 ¶ 3. Specifically, Wyeth provided all then-existing Children's Advil ADE reports to its counsel who then identified the responsive ADE reports pursuant to the Court's December 8, 2003 scope order.[2] DA at 70 ¶ 8; 78 ¶ 3. The segregated ADE reports and previously produced skin reaction ADE reports were returned to Wyeth for inclusion in the S^3 extract. DA at 70 ¶ 8. Wyeth produced 1,023 ADE reports in the S^3 database extract. PA at 274. Additionally, Wyeth produced all of the source documents in its possession for each of those 1,023 ADE reports. DA at 25 ¶ 5; 70 ¶ 9; 75-76 ¶ 3,8; 79 ¶ 4. Wyeth also produced claim notices and lawsuit complaints. DA at 82 ¶ 18.

In February and March, 2004, Wyeth produced the NDAs containing all clinical studies, and over 18,000 pages of supporting data. *See id.* Wyeth also provided CD's with all of the electronic CAMP data and hard copies of thousands and thousands of pages of backup medical information for all of the ADEs within the scope of discovery. *See id.*

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[2] At the January 9, 2004 hearing, Boccuti testified that he believed that there were 1,462 responsive ADE reports. PA at 214. The figure Boccuti gave is, however, the total number of ADEs for Children's Advil or Junior Strength Advil received before July 1, 2002. DA at 70 ¶ 7; 93-94 ¶ 4-5.

In March, and April 2004, Wyeth produced to Plaintiff labels and advertisements for foreign countries from Australia to Venezuela. DA at 79 ¶ 5-6.

E. More Discovery Disputes

Plaintiff later claimed that certain of Wyeth's responses to her subsequent discovery requests were also deficient. Plaintiff did not further challenge any of Wyeth's responses to Plaintiff's first set of document requests. The parties held conferences to discuss Plaintiff's new complaints on January 25, February 8, and October 10, 2005, after the April 18, 2005 close of documentary discovery. The parties were in the process of preparing a JSR briefing the remaining disputes[3] when the Court gave Plaintiff the option to file an omnibus motion addressing all of her complaints or proceed to trial in approximately six months. Plaintiff chose to file this Motion.

III. ARGUMENT

A. Plaintiff's motion for sanctions has no basis in fact or law.

1. Federal law governs discovery and discovery sanctions in federal court.

Plaintiff inexplicably relies on inapplicable Texas and Florida state case law. State law is irrelevant to this Motion. *Redden v. Senior Living Prop. L.L.C.*, 2004 WL 1932861 (N.D. Tex. 2004) (recognizing federal court discovery is not governed by state discovery practice).

2. The discovery sanction of striking a pleading is only for extreme circumstances.

Federal Rule of Civil Procedure 37(b)(2) empowers district courts with the discretion to impose just sanctions on parties who disobey discovery orders. *FDIC v. Conner*, 20 F.3d 1376, 1380 (5th Cir. 1994); *Pressey v. Patterson*, 898 F.2d 1018, 1021 (5th Cir. 1990). This discretion

[3] Plaintiff has alleged that preparation of the JSR took many months because Wyeth intentionally delayed the process. Wyeth did not do so and informed Plaintiff on several occasions that the JSR was complete from its standpoint. Each time, however, Plaintiff added new arguments to the JSR requiring further revisions by both sides. *See* chronology of JSR preparation, DA at 98-103, attached to Susan Hellinger's Declaration, DA at 96-97.

is, however, subject to important limitations. *Id.* The Fifth Circuit admonishes that "[s]anctions should not be used lightly, and should be used as a lethal weapon only under extreme circumstances." *Conner*, 20 F.3d at 1380. Accordingly, to dismiss a case or enter a default judgment as a discovery sanction,[4] the following factors must be present: (1) the refusal to comply must result from willfulness or bad faith and be accompanied by a clear record of delay or contumacious conduct; (2) the violation must be attributable to the client instead of the attorney; (3) the violating party's misconduct must substantially prejudice the opposing party; and (4) a less drastic sanction would not substantially achieve the desired deterrent effect. *Conner*, 20 F.3d at 1380-81 (citations omitted) (finding no record of delay or contumacious conduct sufficient to warrant dismissal and noting that the violating party served supplemental responses before the hearing on the motion for sanctions).

A court's discretion to impose sanctions pursuant to its inherent power is even more limited than its discretion under Rule 37(b). *Pressey*, 898 F.2d at 1021. Such sanctions can only be granted in instances of "bad faith or willful abuse of the judicial process" and "bad faith" in this context is judged by "necessarily stringent" standards.[5] *Id* (determining that there was no instance in which the defendant "directly and in bad faith disobeyed a direct order to produce evidence" and reversing the order striking the defendant's answer).

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[4] Because striking the pleadings of a defendant and rendering a default judgment is equally as harsh a sanction as dismissing a plaintiff's case with prejudice, the Fifth Circuit has stated that it cites cases involving those sanctions interchangeably. *Pressey*, 898 F.2d at 1021 n. 2.

[5] Plaintiff cites unpublished decision *Master Card Internat'l, Inc. v. Moulon*, 2004 WL 1393992 (S.D.N.Y. Jun. 22, 2004) for the proposition that bad faith is not required for the imposition of sanctions. Then, hedging her bets, plaintiff argues that if bad faith is required, the Court should consider prior orders issued in other litigation citing Wyeth for "deliberate destruction of evidence and other acts of discovery abuse." Motion at 21. Those orders do not, however, support Plaintiff's argument. The first order cited from the *Prempro Pruducts Liability Litigation,* PA at 623-24, does not sanction Wyeth for any violation at all. Interestingly, the order does require those plaintiffs to pay $10,800 to Wyeth. PA at 624. Although the next order in Plaintiff's Appendix, also from the *King* case, PA at 625-26, takes judicial notice of decisions in other cases, the *King* court never imposed any sanctions in reliance on that notice. Certainly, Plaintiff would have cited any order doing so. Finally, notably absent from the other order included from the *King* case, PA at 627-28, is any sanctions award; no sanctions were ever awarded in that case.

3. Plaintiff's discovery complaints do not support the imposition of sanctions.

Plaintiff cannot point to any evidence that Wyeth failed to comply with the Court's discovery orders, much less that it did so with willfulness or in bad faith. There is likewise "no clear record of delay or contumacious conduct" or evidence that Plaintiff will be prejudiced by the alleged deficiencies in discovery. At most, Plaintiff's Motion describes minor discovery disputes, most of which are manufactured, and some of which could have been easily resolved. Plaintiff cannot satisfy the elements necessary to impose discovery sanctions.

a. *Wyeth's privileges have not been waived or overruled.*

Claim: Wyeth did not timely assert its privileges in response to 1st RFP Nos. 34 and 35, did not timely produce a privilege log, and has not established its privilege claims. Moreover, the Court has already heard and overruled these privilege claims. Motion at 1-5.

Fact: Wyeth asserted privileges for the safety review documents as soon as they were located and included those documents on its privilege log. Prior to the Motion, Plaintiff never challenged Wyeth's privilege assertions under RFP No. 35 and the Court never considered them.

When Wyeth responded to 1st RFP No. 35, it had not located any responsive documents, and, thus, it did not assert any privilege objections. Later, when collecting documents responsive to more focused requests, Wyeth found responsive documents. Because those documents are privileged, Wyeth asserted the applicable privilege objections.[6]

Wyeth later agreed to and did provide a privilege log to Plaintiff. *See* PA at 435-90. The log was produced as soon as defense counsel could reasonably prepare and produce the log. Plaintiff later claimed that the log was inadequate, but only identified as deficient the fact that the log did not list the requests to which each logged document was responsive. There is no such requirement for privilege logs. *See* FED. R. CIV. P. 26(b)(5). Later, Plaintiff's counsel charged

[6] Wyeth agreed to and did produce safety studies responsive to RFP No. 34. *See* PA at 104.

that the log did not provide enough information for counsel to evaluate the asserted privileges, so Wyeth served an amended log.

Late in the process of preparing the second JSR, Plaintiff asserted that she was challenging all of Wyeth's privilege claims. DA at 102-03. In keeping with federal court practice, once that challenge was made, Wyeth began preparing declarations to support its privilege claims and provided those declarations to Plaintiff's counsel. DA at 103. As the attached declarations show, Plaintiff's challenge of the privileges asserted for the safety review documents and her apparent global challenge of all of the documents identified on the log as attorney work product, Motion at 5, are without foundation. Wyeth hereby tenders for *in camera* review all documents for which privileges and exemptions are claimed and will deliver such documents to the Court when and how instructed.

The privileged documents that are purportedly the subject of the Motion fall into two categories: (1) correspondence among Wyeth's counsel and its employees relating to this lawsuit (the "*Madden* correspondence"); and (2) documents relating to Wyeth's Post-Market Safety Review Meetings. The *Madden* correspondence consists of requests for information and documents among Wyeth's counsel in this suit and counsels' emails and memoranda to various of Wyeth's employees seeking assistance in gathering the requested documents and information. *See* DA at 70-71; 104-12. The *Madden* correspondence, described in the attached Boccuti declarations, is exempt from discovery under the attorney-client privilege and work product doctrine. *See id.*

Documents related to Wyeth's Post-Marketed Safety Review meetings are confidential documents that were prepared in connection with meetings among Wyeth's attorneys, scientists and others regarding the safety of Wyeth's products and whether the products' global

labeling documents should be further addressed. DA at 1-23; 25-26 ¶ 6. These documents are confidential and protected from disclosure by the attorney-client privilege.

Texas Rule of Evidence 503[7] "precludes discovery of confidential communications made between an attorney and client." *Seibu Corp. v. KPMG LLP*, 2002 WL 87461 (N.D. Tex. 2002). The elements of the attorney-client privilege are: "(1) a confidential communication; (2) made for the purpose of facilitating the rendition of professional legal services; (3) between or amongst the client, lawyer, and their representatives; and (4) the privilege has not been waived." *Navigant Consulting, Inc. v. Wilkinson*, 220 F.R.D. 467, 473 (N.D. Tex. 2004); TEX. R. EVID. 503(b). Those elements can be established by affidavit, live testimony or an *in camera* review. *Seibu*, 2002 WL 87461.

As the attached declarations show, and as is evident from a review of the documents submitted *in-camera*, the *Madden* correspondence and the Safety Review Committee Meeting documents meet each of the attorney-client privilege elements. Both categories of documents were intended to be and were kept confidential and, thus, were not disclosed to third parties. *See* DA at 1-23; 25-26; 70-71; 104-12. The communications were made for, among other reasons, safety, regulatory compliance and the purpose of rendering legal services. The *Madden* correspondence was unquestionably made to facilitate the rendition of legal services. Those documents conveyed legal counsel's requests for information and documents generated by this very litigation and the client's representatives' responses to those requests. Likewise, the Safety Review Committee Meeting documents were made for, among other reasons, safety, regulatory compliance, and facilitating the rendition of legal services. That those same documents may have also furthered a business purpose is irrelevant.

[7] In civil diversity actions, like this one, in which state law supplies the rule of decision, privilege issues are determined in accordance with state law. FED. R. EVID. 501.

In both *Siebu* and *Navigant*, this Court held that "[w]here an attorney is functioning in some other capacity—such as an accountant, investigator, or business advisor—there is no privilege." *Seibu*, 2002 WL 87461; *Navigant*, 220 F.R.D. at 474. The Court recognized that the "critical inquiry" in making this determination is "whether any particular communication . . . facilitated the rendition of legal advice to the client." *Seibu*, 2002 WL 87461.[8] Here, the evidence establishes that the Safety Review Committee Meeting documents were communications made for, among other reasons, safety, regulatory compliance and to facilitate the rendition of legal advice. Wyeth's attorneys communicated legal advice related to drug labeling based upon their knowledge of the law and legal experience.

This case is more similar to that of *Electronic Data Systems Corp. v. Steingraber*, 2003 WL 21653414 (E.D. Tex. Jul. 9, 2003). In *Steingraber,* the court determined that the attorneys assisting with an investigation into employee wrongdoing acted in their legal capacity: "The fact that the attorneys may have been hired to facilitate a business decision does not mean that such a decision was devoid of legal consequences." *Id.* The court found that the law firm was retained to contribute its legal expertise to the investigation, including contract interpretation and evaluating the risk of litigation. *Id.* The fact that legal advice is also used for business purposes does not remove the protections of the attorney-client privilege. *See In re LTV Secs. Litig.*, 89 F.R.D. 595, 601 (N.D. Tex. 1981) (holding that "[i]nformation gathered in such a manner as to be privileged does not become discoverable solely because management makes other business use of the information.")

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[8] In *Seibu*, that inquiry could not be answered in the affirmative because the attorney involved was not acting in a legal capacity. Instead, the lawyers hired by KPMG to assist it with an investigation into an allegedly improper audit were involved in an exercise of business judgment. *Id.* In fact, the Court noted that there was no evidence that the lawyers even *saw* many of the documents involved. *Id.* at n. 4. Similarly, in *Navigant*, attorneys were hired to help with an investigation of employees allegedly copying trade secret information. *Navigant*, 220 F.R.D. at 470-71. In that case, however, the Court found that the communications with counsel might well have been made to facilitate legal advice, but the evidence was insufficient to establish that. *Id.* at 474.

The *Madden* correspondence and the Safety Review Committee Meeting documents also meet the final two elements of the attorney-client privilege. The documents were exchanged between Wyeth, its lawyers, and/or its representatives. *See* DA at 1-23; 25-26; 70-71; 104-12. Each Wyeth employee who was privy to the communications was a "representative" within the meaning of Texas Rule of Evidence 503(a)(2). DA at 70-71 ¶ 10.

Federal Rule of Civil Procedure 26(b)(3) provides that documents prepared in anticipation of litigation or for trial by or for a party are exempt from discovery. FED. R. CIV. P. 26(b)(3); *see also Seibu*, 2002 WL 87461. The *Madden* correspondence is work product. Those documents were prepared *during* the course of this litigation. *See* DA at 104-12. Documents created by an attorney acting as an attorney in the very litigation in which the discovery request is made and that discuss the ongoing litigation are protected from disclosure by the work product exemption. *See Robinson v. Texas Auto. Dealers Ass'n*, 214 F.R.D. 432, 440 (E.D. Tex. 2003, *vacated in part*, 2003 WL 21911333 (5th Cir. 2003) (vacating part of the district court's order requiring the disclosure of privileged documents). Thus, the *Madden* correspondence is also exempt from disclosure by the work-product exemption.

Contrary to Plaintiff's assertions, the documents listed on Wyeth's privilege log are protected from discovery by the attorney-client privilege and/or work product exemption. The Court has not previously considered those privileges. Plaintiff tries to read general statements at the hearing into the Court's subsequent order. Motion at 3. The safety review documents were not the subject of, or even mentioned in, either the November 2003 or the January 2004 hearings. PA at 144-92, 207-67. The privilege assertions that the Court considered and rejected were related only to: the S^3 database extract; CAMP 1 and 2 electronic data; and ADE source documents within Documentum. PA at 268-69. Indeed, Plaintiff did not raise any complaint

about 1st RFP No. 35 until October 10, 2005. DA at 80-81 ¶ 12. Thus, Wyeth's privilege assertions for these documents have neither been overruled nor are they in violation of a Court order or a basis for sanctions.

b. *Gerard Boccuti's testimony was accurate and truthful: S^3 is the only database which processes and monitors ADE reports.*

Claim: Boccuti lied under oath at the January 2004 hearing.

Fact: Boccuti was truthful and accurate; S^3 is the only Wyeth database that monitors and processes ADE reports.

Typically, one would expect such a vicious claim to be supported by unassailable evidence. Plaintiff's allegation of perjury, albeit by a different name, is unsupported by facts, and is made without performing an adequate investigation, in reliance on a professional witness whose knowledge admittedly comes from experience with unrelated, prescription drugs.[9]

Plaintiff's claim is based solely on the conjecture included in the affidavits of Plaintiff's counsel and self-proclaimed expert, Keith Altman. Both affidavits are incompetent evidence. *See* Wyeth's response and objections to Plaintiff's evidence. Even if Altman were a properly designated expert witness in this case, his experience in unrelated litigation involving Wyeth prescription diet drugs and Prempro, both manufactured by Wyeth Pharmaceuticals and its predecessors, is irrelevant and inapplicable to this case involving OTC drug Children's Advil, manufactured by Wyeth Consumer Healthcare.

Significantly, much of Altman's affidavit includes information that is incorrect. For instance, Altman avers that Wyeth was ordered to produce all adverse event *data*. PA at 279. The Court's order requires Wyeth to produce all ADEs and underlying source documents, not

[9] Plaintiff's groundless accusations of false testimony and misrepresentations by Wyeth and its counsel are yet another example of Plaintiff's counsel's bluster which has underscored discovery in this case. Throughout the discovery process, Plaintiff's counsel has cursed, made unsupported accusations, and even threatened physical violence, rather than treat witnesses and counsel with courtesy. A few of the countless examples of this conduct can be found in video-depositions excerpts compiled on a CD. DA at 113.

every mention of an adverse event. PA at 194. Additionally, Altman concludes without support that all ADE data in MADIRA are not transferred to S^3. PA at 278. Altman also incorrectly claims that the Court ordered Wyeth to produce the S^3 audit trail. PA at 275. Finally, Altman's claim about what Wyeth's source files "should" include is speculation based on irrelevant experience. After 1996, Children's Advil ADE reports were not processed in CDSSS. DA at 69 ¶ 3. Thus, Altman's assertion that the source documents lack CDSSS worksheets is unfounded.

Boccuti's testimony was neither false nor inaccurate. S^3 is Wyeth's ADE report database. DA at 69 ¶ 2. GSSEL inputs ADE information into S^3 that it receives from various sources, including Wyeth's product quality telephone lines and the databases containing the call-in information. *Id.* Boccuti discussed one such database, WATSIN. He did not discuss one of the others, MADIRA, not only because he was not asked about it, but also because MADIRA and its successor, MAGIC, relate to *prescription* drugs, not OTC drugs, like Children's Advil.[10] *Id.* Moreover, Boccuti was questioned about what databases deal with ADE *reports*. S^3 is the only one. Had he been asked what databases could conceivably contain ADE information, the answer could have been very different, since adverse event information can come from virtually any source all over the world. Regardless, all of that information is transmitted to S^3.

This information is not new to Plaintiff. During the November 2003 hearing, Plaintiff's counsel explained that pursuant to Policy 405, Wyeth employees around the world can report via an intranet ADEs received by other databases. PA at 155. More importantly, Plaintiff's counsel's outraged claim that he "learned within the last couple of months" of MADIRA is inaccurate. Motion at 8; Barber Affidavit, PA at 632, ¶ 3. Plaintiff's counsel has had documents

[10] Altman cites a 483 notice from the FDA which is incompetent evidence. (*See* Wyeth's objections). Moreover, MADIRA is not Wyeth's ADE tracking database.

disclosing the existence and nature of MADIRA since January 7, 2004, when Wyeth produced to Plaintiff, among other documents, its Procedure 401, which defines MADIRA. DA at 82 ¶ 18.

Plaintiff's counsel's awareness of Procedure 401 and knowledge of MADIRA well before the past "couple of months" is evidenced by 7th RFP No. 8, served on Wyeth approximately eight months ago, which sought information and data in MADIRA and referred to Procedure 401. PA at 694. Plaintiff never challenged Wyeth's objections to this request nor addressed the issue of MADIRA's production with Wyeth, raising the issue for the first time in this motion for sanctions. This, despite the fact that at the November 2003 hearing, Plaintiff's counsel stated that if he could get documents like Policy 405 about the other databases describing the kind of information that is in the databases, he could make an assessment "very quickly" about whether to pursue the information. PA at 188.

The true purpose of Plaintiff's Motion is to attempt to reopen discovery and compel the production of an entirely new category of documents. Altman concedes that if a caller were reporting an ADE, the information would be transferred to S^3. PA at 278. Altman claims it is of "paramount importance" to understand what callers were being told in response to general inquiries. PA at 278. Inquiries unrelated to an actual adverse event were not the subject of the hearings before the Court, Boccuti's testimony, or the Court's orders compelling the production of relevant ADE reports. This is a new request for a different type of information. Rather than seeking to compel production of these documents, Plaintiff opted to accuse Wyeth and its counsel of hiding the database and lying to the Court in the hopes that Wyeth's answer would be stricken or additional, eleventh hour discovery would be allowed. There is no justification for the imposition of any sanctions or the allowance of access to Wyeth's databases. This Court should reject Plaintiff's illegitimate efforts simply to rummage through Wyeth's files.

c. *Wyeth produced ADE reports within the scope of the Court's orders.*

Claim: Fewer ADE reports were produced than were represented to exist, therefore, evidence has been withheld.

Fact: Evidence has not been intentionally withheld from discovery.

At the January 2005 hearing, Boccuti testified that there were 1,462 ADE reports within the Court's scope order. Plaintiff claims Wyeth only produced 1,023 reports, therefore, 439 must have been withheld. Motion at 11. Plaintiff also complains, based upon Altman's conjecture, that Wyeth submitted responsive ADEs to the FDA that were not produced to Plaintiff. *Id.* at 12.

Plaintiff is correct that Wyeth produced 1,023 ADE reports in the S^3 data extract. Boccuti's estimate that there were "on the order of about fourteen hundred" responsive ADEs, PA at 214, was inaccurate. DA at 70 ¶ 7; 93-94 ¶ 4-6. S^3 contained 1,462 *total* ADE reports for Children's Advil, including Junior Strength Advil, as of July 1, 2002. *Id.* Not all of those 1,462 reports, however, relate to the minor plaintiff's symptoms. *Id.* Responsive ADE reports were segregated from that total and produced to Plaintiff in the S^3 extract along with existing source documents in Wyeth's possession for those 1,023 ADE reports. DA at 25 ¶ 5, 70 ¶ 8-9, 76 ¶ 8. Additionally, through the process of investigating the Motion, Wyeth found three ADE reports that were inadvertently not produced.

Altman's list of ADE reports submitted to the FDA but not produced includes ADEs that refer to symptoms not within the Court's order, such as anaphylactic shock, and ADE reports for products other than Children's Advil. *Compare* PA at 274 to PA at 198-202; *see also* DA at 24-25 at ¶ 3-4. In fact, Altman found only three ADE reports within the discovery scope that were overlooked during the review process. Wyeth will produce those three documents.[11]

[11] Wyeth's investigation and additional production would have been done sooner if Plaintiff had contacted defense counsel regarding the issue rather than first bringing it up in a motion for sanctions. DA at 80 ¶ 9.

d. *Wyeth produced the underlying source documents.*

Claim: Wyeth did not produce the source documents for each responsive ADE report.

Fact: All of the source documents for the responsive ADE reports have been produced.

Wyeth produced from the Documentum database all of the underlying source documents for the ADE reports in the S^3 data extract as required by the Court's order. DA at 70 ¶ 9; 76 ¶ 8; 79 ¶ 4. Upon investigating Plaintiff's earlier complaint that Wyeth did not produce all source documents, defense counsel discovered that all of the source documents were not in Documentum; some were in storage. DA at 79 ¶ 4. Wyeth retrieved the documents and produced them to Plaintiff. DA at 25 ¶ 5. Plaintiff has all the source documents that Wyeth possesses for the ADE reports originally produced.[12] *Id.* DA at 70 ¶ 9; 76 ¶ 8.

e. *Foreign labels have been produced and related documents that have not been produced are now being collected and will be produced to Plaintiff.*

Claim: Wyeth delayed producing foreign labeling and some foreign labeling is still missing.

Fact: Wyeth gathered and produced all foreign labels. Only a miscommunication prevented the other documents Plaintiff seeks from being produced, many of which have now been produced.

While conceding that Wyeth "produced the majority of foreign labeling . . . on Mar. 9, 2004," Plaintiff nevertheless alleges that Wyeth delayed in producing the remaining labels. Plaintiff also alleges that Product Information Leaflets ("PILs") and Summaries of Medical Product Characteristics ("SmPCs") for a number of countries have not been produced and alleges, for the first time, that she does not have all of the foreign labeling for the years prior to the minor plaintiff's injuries. Motion at 14-15; DA at 80 ¶ 12.

[12] On October 21, 2005, Wyeth supplemented discovery with the 154 ADE reports created after the original production. Attendant source documents will be produced upon being gathered and redacted. DA at 81 ¶ 13.

As noted in the Court's December 8, 2003 order, Wyeth "*agreed* to give Plaintiff all foreign labeling and foreign warnings." PA at 195 (emphasis added). Wyeth produced a multitude of foreign labels to Plaintiff. DA at 79 ¶ 5-6.

Subsequently, around March 2005, about a year after the majority of the foreign labels were produced, Plaintiff complained that not all foreign labels were produced. Accordingly, Wyeth requested that all foreign affiliates provide their labels a second time. DA at 114 ¶ 3. Additional labeling from three countries was located and produced. DA at 79 ¶ 7.

Later in 2005, Plaintiff again alleged deficiencies in Wyeth's production of foreign labels. This time, she identified as specifically missing the foreign package inserts or the PILs and SmPCs. DA at 80 ¶ 8. Wyeth's investigation of this complaint revealed that, in fact, only a few countries' PILs and SmPCs were produced. This was presumably due to language barriers and the different terminology used by various divisions and countries—when Wyeth requested "labeling" from its foreign affiliates, they gathered and provided only what they consider to be "labels": the actual artwork on the product container. Wyeth has since clarified the instructions to its foreign affiliates and is in the process of obtaining the foreign package inserts. DA at 114-15 ¶ 3-4; 80 ¶ 8. Some inserts were produced on November 9, 2005, including the PILs for Belgium, the Netherlands, and Luxembourg. *Id.* More will be produced as Wyeth receives them.

In sum, in early 2004, Wyeth produced the foreign labels for Children's Advil within the scope of discovery. When Plaintiff questioned the sufficiency of the production, Wyeth investigated and produced three missing labels to Plaintiff. When Plaintiff raised the issue of

missing package inserts[13], Wyeth immediately confirmed the accuracy of Plaintiff's complaint, determined that the problem resulted from an unintentional miscommunication, and corrected that miscommunication. Responsive documents have since been provided to Plaintiff and more will be provided as they are collected. Wyeth has not willfully disobeyed any Court order, and there is no basis for imposing discovery sanctions.

f. *Policies regarding compliance with FDA reporting procedures for ADEs were produced soon after they were located.*

Claim: Wyeth improperly produced some of its safety policies and procedures after Plaintiff deposed Wyeth's employees.

Fact: Wyeth produced over 200 pages of its safety procedures in December 2003. Wyeth produced other safety policies later, when they were discovered.

Plaintiff's complaint regarding production of some of Wyeth's safety policies distills down to a nonsensical charge that Wyeth's fulfillment of its duty to supplement upon locating additional documents is an abuse of the discovery process. Plaintiff's counsel relies on his own incompetent affidavit as support for the irrelevant point that "all Wyeth employees testified that there were no written policies assigning any one person to review the literature and no written corporate directive requiring anyone to review ADEs to determine if they constituted a safety signal requiring a label change." Motion at 15. Plaintiff's counsel's interpretation of the testimony is conclusory and hearsay, and is belied by the complete testimony of the witnesses themselves.[14] In fact, Plaintiff's questions to Dr. Ewell during his January 13, 2005 deposition

[13] Plaintiff's allegations that Wyeth delayed producing the French PIL are particularly noxious. Motion at 14; PA at 633. Wyeth produced the new French PIL to Plaintiff before it went into use, since Plaintiff was about to depose Dr. Roujeau in Paris, and may have wanted to question him about that document. DA at 80 ¶ 8.

[14] While Dr. Ewell testified no policy required "any one individual" to search for medical literature, much of his additional testimony is omitted from Plaintiff's rendition of the facts. *See* e.g. DA at 121-24. Importantly, he testified that the entire analgesic therapeutic team was responsible for literature review and pharmacovigilance. DA at 125-31. Dr. Berlin testified that he would have to "go back and look" at Wyeth's Standard Operation Procedures to determine whether any existed that required any one individual to search medical literature. DA at 137-41.

about Wyeth's policies, and his transcript review jogged his memory about where to locate old policies. DA at 117. Wyeth supplemented its production with the policies.[15] DA at 81 ¶ 15.

g. *Lawsuits within the scope of the Court's orders have been produced.*

Claim: The Court ordered Wyeth to produce "all information pertaining to lawsuits, notice, labeling claims, all that stuff pertaining to the symptoms alleged in the case" involving Adult Advil. Wyeth has not produced all of the "information pertaining to lawsuits including petitions, depositions, or other labeling dealing with Adult Advil." Motion at 16.

Fact: Wyeth produced all petitions, complaints, and claim letters for adult Advil relating to the symptoms alleged by the minor plaintiff. The Court's orders did not require production of all information, depositions, or "other labeling dealing with Adult Advil."

Plaintiff again tries to misconstrue the Court's orders. Tellingly, Plaintiff does not cite to the orders themselves, only to a portion of the hearing transcript. PA at 180-81. Regarding lawsuits, the Court ordered Wyeth "to produce all lawsuits, notices of claims, labeling, and warnings dealing with adult Advil, again dealing with the symptomatology that plaintiff Labrea Williams suffered . . ." PA at 195. Wyeth produced those documents. DA at 82 ¶ 18.

h. *Wyeth supplemented its production of the NDAs.*

Claim: Wyeth has a duty to supplement its discovery responses, but has refused to supplement its production of the NDAs for Children's Advil.

Facts: Wyeth agreed to and did supplement its production of the NDAs.

Wyeth agreed in writing to supplement its discovery responses as required by the federal rules. PA at 576. Additionally, at the October 10, 2005 conference, defense counsel informed Plaintiff's counsel that the NDAs would be supplemented. DA at 80-81 ¶ 12. On November 4, 2005, Wyeth supplemented its production of the Children's Advil NDAs. DA at 81 ¶ 13.

[15] Plaintiff's counsel accuses defense counsel of not "adequately responding" to his demand to know why the documents were produced "so late." Motion at 15. Defense counsel declined to respond to Plaintiff's counsel's rude e-mail containing curse words, PA at 516, 517, which followed numerous requests for Plaintiff's counsel to cease engaging in such discourteous and unprofessional conduct. *See* DA at 83-91. Nonetheless, Plaintiff's counsel did not mention this issue again until it appeared in a draft motion for sanctions. DA at 81 ¶ 15.

i. *All ADE report versions exist and all ADE information for each version is in Plaintiff's possession.*

Claim: Wyeth destroyed early versions of ADE reports thereby spoliating evidence.

Fact: Boccuti was correct. Dr. Williams was mistaken. S^3 maintains all versions of the ADE reports and keeps a record of removed or "voided" information that is in Plaintiff's possession.

Plaintiff claims that the S^3 database extract in her possession only contains the last version of the ADE reports so it is impossible for Plaintiff to see how the reports evolved over time. Motion at 12. Plaintiff's spoliation allegation is based on discrepancies between testimony given by Boccuti that S^3 tracks changes or deletions, and the testimony of Dr. Patricia Williams of Wyeth allegedly agreeing with the questioner that prior versions of the ADEs are "overwritten." Motion at 18. Despite the fact Dr. Williams's deposition was taken in November 2004, this alleged discrepancy was not addressed with defense counsel until Plaintiff gave him a draft sanctions motion. DA at 80-81 ¶ 12. Rather that accept the facts offered by defense counsel—facts that would have been known to Plaintiff had she taken the time to understand the database extract provided to her—Plaintiff filed a motion for sanctions accusing Wyeth of spoliation.

Plaintiff's spoliation accusations are baseless. As a threshold matter, Plaintiff's legal analysis concerning spoliation is wrong. Texas authority does not apply to this proceeding. *See Washington v. Department of Transp.*, 8 F.3d 296, 300 (5th Cir. 1993) (federal evidentiary principles apply in diversity cases). In the Fifth Circuit, an adverse inference based on the destruction of potential evidence—must be predicated on the defendant's "bad faith." *See United States v. Wise*, 221 F.3d 140, 156 (5th Cir. 2000); *Caparotta v. Entergy Corp.*, 168 F.3d 754, 756 (5th Cir. 1999). The two conditions precedent to a finding of spoliation are (i) destruction of evidence; and (ii) bad faith. *Wise*, 221 F.3d at 156. Despite Plaintiff's insistence to the contrary,

"[m]ere negligence is not enough, for it does not sustain an inference of consciousness of a weak case." *Vick v. Texas Employment Comm'n.*, 514 F.2d 734, 756 (5th Cir. 1975).

Plaintiff cannot establish either (i) the destruction of any evidence, or (ii) any bad faith on the part of Wyeth. First, Wyeth has not destroyed any evidence. Boccuti's testimony at the hearing was correct: S^3 does maintain prior versions of ADE reports and an audit trail. DA at 75-77 ¶ 4-5, 10-11. Dr. Williams, who only has access to view the current version of an ADE report on her computer, was unaware of these facts at the time of her deposition. DA at 73 ¶ 6-9. Had Plaintiff reviewed the materials produced to her in the source documents and S^3 database extract, she would have seen the prior version information for ADE reports that she claims has been withheld or destroyed.[16] *See* 76 ¶ 9. Indeed, most of Plaintiff's concerns could have been addressed long ago if she had made an effort to conduct other forms of legitimate discovery (*e.g.*, a corporate representative deposition to learn how the database extract works).

Plaintiff's new request for an "audit trail" is improper. "Audit trails" are not synonymous with "versions." DA at 75-77 ¶ 4-11. Plaintiff did not previously request audit trails, and they were not addressed during prior discovery hearings (other than to explain their existence) or in the Court's discovery orders.[17] *See* PA at 144-96, 207-70. Altman's and Plaintiff's use of the terms "version" and "audit trail" virtually interchangeably is either an attempt to mislead the Court or an improper attempt to reopen discovery and obtain a new category of documents. Additionally, Plaintiff incorrectly charges that case messages were not produced. Motion at 18. Case messages for the ADE reports in the S^3 data extract were printed and produced. DA at 76 ¶

[16] All ADE information from various versions is included in the S^3 database extract or their source documents. The only information for versions prior to the maximum version in existence at the time the S^3 data extract was created that was not included pertained to two tracking fields. DA at 76 ¶ 9.

[17] If Plaintiff had requested audit trails, Wyeth would have objected to providing them on the grounds of undue burden and expense. To prepare an audit trail for a *single* ADE report costs between $800 and $14,800. DA at 77 ¶ 11. Accordingly, the cost of providing an audit trail for all ADE reports produced is prohibitive.

8; 79 ¶ 4. In sum, there has been no destruction of evidence, and there is no basis—factually or legally—for imposing sanctions on Wyeth for allegedly spoliating evidence.

j. *Wyeth has not "over-redacted" documents.*

Claim: Wyeth has "over-redacted" documents and failed to provide an audit trail to Plaintiff showing every redaction made to every document and database.

Fact: In keeping with the Court's orders, Wyeth only redacted confidential information from the relevant documents as required by law and will provide an audit trail as required.

Citing the affidavit of her counsel, Plaintiff complains that Wyeth has not provided an audit trail for every redaction ever made in this case in violation of a court order and requests that Wyeth be ordered to provide such an audit trail. Motion at 19. To the contrary, from ADE reports and source documents, Wyeth only redacted confidential information as required by law and permitted by the Court's order and is providing the required audit trail. DA at 79 ¶ 4; 80 ¶ 10; 82A. From PSURs, Wyeth redacted the same confidential information and ADE reports not within the Court's scope of production order. DA at 82 ¶ 18.

The Court instructed Wyeth to redact patient and reporter identifying information and "provide an audit trail" limited in scope to "any patient or reporter identification information redacted, sufficient to show what was redacted, by whom, and why" for the data in the S^3 extract; the data from the CAMP 1 and CAMP 2 databases; and the underlying medical records and reports from the Documentum database. PA at 268-69. The audit trail order did not encompass every document produced in this case. *See id.*

Wyeth redacted the confidential information in accordance with this Court's order. Defense counsel concedes that in concentrating on proper and prompt production of thousands of documents, he inadvertently forgot to provide the audit trail as required. DA at 80 ¶ 10. Defense counsel has attached to his declaration an audit trail states that these redactions were made, by whom (Vinson & Elkins attorneys) and why (federal regulation mandates). Because

counsel's mistake was not willful or in bad faith, resulted in no prejudice to Plaintiff, and has been corrected, it does not justify the imposition of any sanctions.

B. Plaintiff's motion to compel should be denied in all respects.

Plaintiff's Motion to Compel challenges only certain of Wyeth's objections and privilege assertions. Accordingly, Wyeth will only address those challenges or issues requiring particular highlighting, but it incorporates by reference herein all of its previously asserted objections and privileges as if fully set forth at length.

1. Document Requests

a. *The rules do not require a producing party to identify documents by Bates number.*

Wyeth produced thousands of its documents as those documents are kept in the usual course of its business. Plaintiff's second through seventh sets of requests for production seek subsets of many of the documents already produced. In response to those repetitive and overlapping requests, Wyeth responded that the documents were already produced. Plaintiff argues without citation to any authority, that it is Wyeth's burden to locate and identify the documents Plaintiff wishes to find. The law imposes no such burden on Wyeth.

Federal Rule of Civil Procedure 34 provides: "[a] party who produces documents for inspection shall produce them as they are kept in the usual course of business *or* shall organize and label them to correspond with the categories in the request." FED. R. CIV. P. 34(b) (emphasis added). Which manner of production to use is the producing party's choice. *Rowlin v. Alabama Dept. of Public Safety*, 200 F.R.D. 459, 462 (M.D. Ala. 2001) (finding that the magistrate judge abused her discretion in requiring the producing party to produce documents in a manner other than how they are kept in the usual course of business).

Plaintiff's protestation that "there have been some 140,000 of pages of documents produced and plaintiffs cannot reasonably be expected to blindly dig through them in hopes of stumbling onto those that might be responsive to any given request" does not alter the express terms of Rule 34(b) and impose upon Wyeth the obligation to identify specific documents for Plaintiff. Motion at 23. Courts have considered and rejected similar complaints.[18]

Likewise, the fact that Plaintiff has served multiple requests seeking the same documents does not alter the burdens. If that were so, Rule 34(b) would be meaningless. Any time a requesting party were faced with thousands of pages of the documents it thought it wanted, but, upon receipt, did not want to organize, it could send a second request for the same documents to force the producing party to do the requesting party's homework by organizing and identifying the desired documents. Given this nonsensical result, it is not surprising that courts reject this argument. *See, e.g.*, *Liddell v. Board of Educ. of St. Louis*, 771 F. Supp. 1496, 1499 (E.D. Mo. 1991) (ruling that the requesting party's inability to find what it wanted was not the fault of the producing party. "The [requesting party] requested everything under the sun and the [producing party] gave them access to it all. The [producing party] was not obligated to wrap up the volumes of data into neat little packages for the [requesting party]."; *Hagemeyer N. Am., Inc. v. Gateway Data Scis. Corp.*, 222 F.R.D. 594, 596-98 (E.D. Wis. 2004) (holding that a producing party properly responded to a second request by stating that all responsive documents had already been produced and rejecting the requesting party's argument that that the producing party had a duty to segregate the material requested from the nonresponsive documents).

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[18] *See In re G-I Holdings, Inc.*, 218 F.R.D. 428, 439 (D.N.J. 2003) (finding no obligation on the part of the party who produced 200,000 pages of documents as those documents were kept in the usual course of business to specify which documents, if any, were responsive to which requests); *see also Jobe v. ATR Mktg., Inc.*, 1998 WL 252382, *2 (E.D. La. May 15, 1998) (distinguishing between Rule 33(d) which does require a party referring to documents in lieu of providing interrogatory answers to be specific, with Rule 34(b) which has no such requirement).

Wyeth has discharged its duty to respond to Plaintiff's 149 requests for production and Plaintiff's request to impose greater obligations than the Rules dictate should be denied.

b. *2nd RFP No. 9: Medical personnel or consultants' notes or reports.*

Plaintiff's request for all notes and reports of Wyeth medical personnel or consultants evaluating all of the over 1,000 ADEs produced is overly broad and unduly burdensome and expensive. As an initial matter, when requests for production are propounded to a company, it is the *company* which must respond to those requests. The company is only obligated to produce documents, subject to its objections, which are in its possession, custody and control. FED. R. CIV. P. 34(a). Corporate documents in the possession of a company's former employees are not in the company's control unless those employees still receive compensation from the company—and even compensation is not determinative of control. *See In re Folding Carton Antitrust Litig.*, 76 F.R.D. 420, 423 (N.D. Ill. 1977) (noting that compensation is only an indicia of control).

More importantly, responding to Plaintiff's incredibly broad request would impose an undue burden and extraordinary expense on Wyeth. In order to determine if outside medical consultants were even contacted by Wyeth in connection with the ADEs, someone authorized to access and trained on S^3 would have to review every one of the more than one thousand ADEs produced as well as each ADE's attendant source documents. DA at 147 ¶7-9. Wyeth estimates that retaining qualified persons to conduct such a review would cost Wyeth at least $41,250, plus additional overhead. DA at 147¶ 10-11. Further, once the documentation regarding each ADE had been reviewed and any consultants identified, Plaintiff's request would require Wyeth to contact each consultant if possible, and request any responsive documents—*if* the consultant is willing to cooperate—which would no doubt pose additional burden on Wyeth.

Moreover, the extreme burden imposed by Plaintiff's request far outweighs any benefit the information likely to be obtained by the process would yield. The information obtained from

outside medical consultants likely appears in the ADE source documents in Plaintiff's possession. DA at 148 ¶ 12. There is no justification for forcing Wyeth to do Plaintiff's investigation and determine if any outside consultants were used when the burden on Plaintiff is the same as that of Wyeth.[19]

c. *2nd RFP Nos. 24 and 26: Documents showing Wyeth's annual profit on Children's Advil and gross sales.*

RFP Nos. 24 and 26 are overly broad and seek documents not reasonably calculated to lead to the discovery of admissible evidence. Plaintiff seeks *any* document showing the Wyeth's annual profit on Children's Advil sales. Without conceding that documents relating to annual product profit and sales data are relevant, requests seeking *every* such document are overly broad. Moreover, documents showing profits from the sale of Children's Advil do not relate to the issues of malice and punitive damages in any way, and comparisons of Wyeth's profits to its safety, marketing and research expenditures have no bearing on this case. Wyeth produced annual reports containing the financial information to which Plaintiff is entitled under the law.

d. *2nd RFP No. 27: Materials warning of a causal relationship or probable association between Children's Advil and SJS, TEN, or acute renal failure.*

Plaintiff's request is based upon a disputed premise. Wyeth does not agree that there *is* a definitive causal relationship, or probable association between Children's Advil and SJS, TEN or acute renal toxicity. Accordingly, Wyeth has no documents warning of such a causal relationship. Subject to its objections, Wyeth responded that Children's Advil labeling addressing any potential association is included in the NDAs produced in this case.

e. *3rd RFP Nos. 9, 12, 13, & 16 and 4th RFP Nos. 3, 4, & 6: Documents allegedly remaining to be produced.*

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[19] Wyeth offered as a *compromise* that if Plaintiff would limit her request to SJS and TEN ADE reports, Wyeth would agree to determine if consultants were contacted and then contact the consultants and attempt to obtain such notes and reports. Plaintiff refused this offer, yet criticizes Wyeth for not performing under it. Motion at 24.

Plaintiff claims that responsive documents have been tendered, but not produced. Motion at 25. Plaintiff is incorrect. All non-privileged documents responsive to 3rd RFP No. 9 have been produced. Regarding 3rd RFP Nos. 12, 13, and 16 and 4th RFP Nos. 3, 4 and 6, Wyeth served supplemental responses producing the responsive documents as promised. DA at 149-54.

f. *4th RFP Nos. 7 & 8: PowerPoint presentations presented to management.*

Plaintiff claims that Wyeth has asserted unsupported privilege objections to these requests. Motion at 25. Wyeth originally asserted privilege objections but withdrew those assertions during the drafting of the JSR. Wyeth does, however, stand on its objections as to the presentations' relevance and over breadth. The PowerPoint presentations presented to management, those used by sales people, and the marketing department's plans are not reasonably calculated to lead to the discovery of admissible evidence. Moreover, the requests are overly broad in temporal scope. Plaintiff seeks presentations given as far back as 1995 although the minor plaintiff was not even given Children's Advil until 2002. Further, Plaintiff already has Wyeth's sales manuals, and there is nothing to indicate that the PowerPoint presentations will provide Plaintiff with any information she does not already have.

g. *5th RFP Nos. 1, 2, & 3: Labeling Committee Minutes*

The Wyeth Consumer Healthcare Labeling Committee ("LC") was created in 2004. DA at 115. LC minutes dated post-June 1, 2002, the minor's date of ingestion, are not reasonably calculated to lead to the discovery of admissible evidence, FED. R. EVID. 403, 407. Moreover, Plaintiff's request is not limited to the required scope. *See* PA at 678-80. Most importantly, LC minutes in existence record attorney-client privileged communications. DA at 115 ¶ 6-10.

h. *5th RFP Nos. 4, 5, 6, & 7: Annual and Periodic NDA Reports*

Documents responsive to 5th RFP Nos. 4, 5, 6, and 7 were produced in early 2004 when Wyeth produced the NDAs. PA at 680. After Plaintiff complained she lacked some of these

documents, Wyeth produced them a second time at the January 12, 2005 deposition of Elizabeth Ashraf. DA at 157-59. When this issue was discussed at the October 2005 conference, defense counsel explained that responsive documents had indeed been produced. DA at 80-81 ¶ 12. Plaintiff should be required to familiarize herself with the documents in her possession before filing baseless motions for sanctions and to compel.

i. *6th RFP No. 1: Safety review and other documents.*

Plaintiff argues documents responsive to 6th RFP No. 1 relate to the minor plaintiff's symptoms and are therefore relevant, Motion at 32, but ignores that Wyeth's relevancy objection is targeted at the portion of the request seeking documents pertaining to a foreign label change. Relevancy aside, the documents, are privileged. *See* DA at 1-23; 25-26 ¶ 6. *See also,* discussion at III.A.3.a. *supra.*

j. *7th RFP: Generally*

As a preliminary matter, in addressing the 7th RFP, Plaintiff virtually ignores the fact that Wyeth objected to almost every request as harassing since most of the requests were duplicative of prior requests and many others were drafted in a manner to obtain documents without regard to the Court's scope of production order.[20] Plaintiff simply ignores these and other valid objections which by themselves sufficiently obviate any duty to respond.

k. *7th RFP Nos. 1, 2, 40 & 41: Documents allegedly tendered, but not produced.*

Plaintiff's complaints are meritless. Wyeth has produced the documents responsive to 7th RFP Nos. 1 and 2. PA at 690-91. Seventh RFP No. 40 seeks documents tendered to Plaintiff's counsel at Dr. Stern's deposition that Plaintiff's Counsel admitted he already had. DA at 179. Wyeth's counsel reminded Plaintiff's counsel of that rejected tender at their meeting

[20] If the harassing nature of the requests were not evident from a mere reading of them, the intent to harass is plain from Plaintiff's letter transmitting them which closes with the taunt "Enjoy." DA at 92.

prior to the Court's pre-trial conference, and yet No. 40 still found its way into the Motion. DA at 80-81 ¶ 12. Regarding 7th RFP No. 41, Plaintiff has had the PIL for the United Kingdom since at least March 9, 2005 and the PIL for France since April 22, 2005. DA at 80 ¶ 8; *see also supra* at § III.A.3.e. Wyeth produced the Dutch PIL (and many others) on November 9, 2005, DA at 80 ¶ 8, and is in the process of obtaining the German PIL and will produce it as soon as it is obtained. *See supra* § III.A.3.e.

l. *7th RFP Nos. 1 & 2: ADEs and source documents.*

These requests are duplicative of the requests in the 1st RFP seeking ADEs. ADE reports have been the subject of two hearings and two Court orders. Plaintiff has the responsive ADE reports and their source documents. *See supra* at § III.A.3.c.

m. *7th RFP Nos. 3-5, 9, 14, 15, 18-25, 29-31, 35 & 39: Multiple unrelated requests and French documents.*

Labeling documents have been produced and most of the PILs and SmPCs have been produced. *See supra* at § III.A.3.e. Plaintiff then addresses French documents, production of which is not possible pursuant to the French "blocking statute." *See* Law No. 80-538, Relating to the Communication of Economic, Commercial, Industrial, Financial, or Technical Documents or Information to Foreign Natural or Legal Persons, 1980 J.O. 1799, 1980 D.S.L. 285 (Fr.) (prohibiting any person from requesting, seeking, or disclosing commercial, industrial, technical and other documents or information leading to the constitution of evidence with a view to foreign judicial or administrative proceedings, subject to treaties or international agreements).

n. *7th RFP No. 3: All versions of Dr. Julien's report.*

Plaintiff offers no evidence that Dr. Julien is under Wyeth's control because she cannot. In a previous teleconference, the Court acknowledged that Dr. Julien's deposition attendance could not be ordered since he was not in Wyeth's control. Wyeth produced the only version of

Dr. Julien's report in its possession in the United States, and the French blocking statute, *supra*, restricts production of versions that may be in the possession of Wyeth's French affiliate.

o. *7th RFP Nos. 4, 6-8, 16, 17, 19-22, 24-28, 30-36 & 38: Unrelated requests.*

Plaintiff challenges only Wyeth's work product assertions for these requests. Documents responsive to RFP Nos. 4, 6, 24, 25, 26 and 32 are, however, privileged. *See, supra* § III.A.3.a.[21]

p. *7th RFP No 34: S^3 cases transmitted via e-mail on January 30, 2004.*

Wyeth has determined that the responsive documents are not privileged. All responsive ADE reports (save the three additional ADEs that will be produced) have been produced, and specific ADEs attached to a particular e-mail are irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

q. *7th RFP Nos. 12, 13 & 40: Drs. Stern's and Roujeau's communications and data.*

Seventh RFP Nos. 12 and 13 are duplicative of document requests served upon Drs. Stern and Roujeau themselves and seek documents tendered at their depositions. *See, e.g.*, DA at 166-78, 188-91. 7th RFP No. 40 seeks documents Plaintiff already has. *See supra* at § III.B.1.k.

2. Interrogatories

a. *Interrogatories served by the minor plaintiff.*

Wyeth withdraws its objections to the minor plaintiff serving interrogatories on Wyeth but retains its other objections, some of which were challenged by Plaintiff as discussed below.

b. *Interrogatory Nos. 1-10: Contention interrogatories.*

Although contention interrogatories are permitted under Federal Rule of Civil Procedure 33(c), they should not be overbroad or unduly burdensome. *See* FED. R. CIV. P. 26(b)(2); *see also Steil* v. *Humana Kansas City, Inc.*, 197 F.R.D. 445, 447 (D. Kan. 2000) (holding that

[21] Despite the harassing nature of the requests, Wyeth has nonetheless been able to confirm that there are no documents responsive to 7th RFP Nos. 7, 16, 17, 19, 20, 21, 27, 30, 33, 34, and 36 protected by work product.

contention interrogatories seeking "every fact and document" were overly broad and unduly burdensome). Plaintiff's contention interrogatories ask Wyeth to "state all facts and identify all documents" supporting its contentions, PA at 732-38, and as such, are overly broad and unduly burdensome. Moreover, requests for identification of "all documents" supporting Wyeth's contentions call for the identification of counsel's mental processes, which are attorney work-product. In any event, contention interrogatory responses may refer the propounding party to expert reports and depositions. Significantly, Plaintiff did just that. *See, e.g.,* DA at 198-202.

c. *Interrogatory No. 11: Opinions of Wyeth employees.*

Rule 26(a) requires expert reports only from retained experts or employees whose duties regularly involve giving expert testimony. FED. R. CIV. P. 26(a)(2)(B). Plaintiff seeks to skirt that rule by using an interrogatory to obtain the opinions of non-retained individuals and Wyeth employees who do not regularly give expert testimony. Regardless, those individuals have not been asked to form any expert opinions about this case. Whether they provide any opinions will depend upon questions asked at trial. Accordingly, not only is Wyeth not obligated to provide this information, but the information does not yet exist.

d. *Interrogatory Nos. 12-14: Wyeth's sales, profits and expenses are irrelevant.*

Wyeth's annual profits from the sale of one particular drug and its sales and expenses are irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. *See supra* at § III.B.1.c.

3. Requests for Admission

a. *RFA Nos. 5, 7-10, 12, 21, 38, 40, 43 & 52: Lack of evidence does not require an admission.*

Plaintiff takes the absurd and unprecedented position that Wyeth should be forced to admit requests for which there is no evidence, inconclusive evidence, or to which any answer

would be speculative. Plaintiff's example, RFA No. 5, illustrates the impropriety of the requested relief: "Admit that the product in question reached the plaintiff in this case in substantially the same condition in which it was sold." PA at 744. Plaintiff argues that since there is no evidence to suggest that it did not, Wyeth's refusal to admit this point is "pure speculation." Motion at 28. Of course, the reverse is also true. Since there is no definitive evidence that the product *reached* Plaintiff substantially in the condition it was sold, any admission would also be speculative. The other requests are similar. There is no support for the argument that a party can be forced to make admissions under these circumstances, and Plaintiff is not relieved of her burden to prove her case by a preponderance of the evidence.

b. *RFA Nos. 20-22, 24, 28-30, 32, 35-37, 40, 41, 44, 54, 55, 61, 64, 68, 73, 74, 77, 78, 85, 90, 100-13, 117, 118, 120, 124, 128, 129, 132 & 133: Objections and responses were properly made.*

Without truly addressing the merits of Wyeth's objections, Plaintiff challenges the fact that objections were made and that some responses were qualified. Motion at 29-31. However, Rule 36 permits objections and specification, in good faith, that only a portion of an admission is true and to qualify or deny the remainder. FED. R. CIV. P. 36(a). In accordance with the Rules, Wyeth objected and then responded in good faith, admitting as much of the requests as it could.

c. *RFA Nos. 50, 51 & 117: Requests for admission without foundation.*

Plaintiff asserts without argument or authority that Wyeth's foundation objection to these RFAs is itself without foundation. Motion at 31. Because these requests indeed lack foundation, Plaintiff is unable to provide support for overruling those objections. Moreover, Wyeth asserted other, valid objections to these three same requests that Plaintiff did not address.

d. *RFA Nos. 115 & 116: Burdensome business records admissions.*

Again, Plaintiff improperly tries to force admissions. Wyeth denied RFA No. 115 because as the Motion admits, NDAs contain documents that Wyeth does not create in

the regular course of its business. *See* Fed. R. Evid. 803(6). In response to RFA No. 116, Wyeth denied that every document it produced is its business record. Both requests impose an undue burden to identify all pages that are business records. DA at 81-82 ¶ 16-17.

IV. CONCLUSION

Defendants pray that this Court hold a hearing on Plaintiff's Motion, deny Plaintiff's Motion, and award such other and further relief, general and special to which Wyeth is entitled.

Respectfully submitted,

Joseph Cohen w/permission by Mark Pryor

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing document has been served upon counsel for Plaintiff, James Barber and Charles Valles via hand delivery on the 14th day of November, 2005.

Joseph Cohen w/permission by Mark Pryor
Joseph D. Cohen
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